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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/884,729 | 06/19/2001 | Luis A. Davila | CRD-0938 | 2529 |

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| EXAMINER |
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GILPIN, CRYSTAL M

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,729

Applicant(s)

DAVILA ET AL.

Examiner

Crystal M Gilpin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: The word -curvature- is misspelled in "having a radius of curvanture" in the second line of claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being ^{unpatentable} ~~anticipated~~ ^{over} ~~by~~ Globerman et al. (WO 97/33534) in view of Boatman et al. (USPN 5,632,771).

Regarding claims 1-6, 9, 10 and 12-14, Globerman et al. disclose of a intraluminal medical device (Figures 10-12) made of a material such as nitinol, with a first collapsed diameter that is expandable to a second anchoring diameter, with at least one marker housing (Ref. Number 29) and marker insert (Ref. Number 25) with the equal radii of curvature. The marker insert (Fig. 11, Ref. Num. 37) is substantially cylindrical to fit within the substantially tubular marker housing (Fig. 11, Ref. Num. 35). Nitinol is well known in the art as a superelastic alloy that is comprised of about 50% Nickel and the remainder Titanium. Globerman et al. further disclose that the marker housing is an integral part of the medical device structure (Figure 10), is made of the same material as the device and that the insert material is a different material such as tantulum (Page 3, Lines 5-6) and has a higher radiopacity than the device material. However,

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Globerman et al. lack the teaching of the at least one marker extending from the substantially tubular member. Boatman et al. teach of a flexible stent or tubular member with at least one marker connected to and extending from the tubular member (Figure 1, Ref. Numbers 41 and 42) to aid in the positioning of the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Globerman et al. to have the markers extend from the tubular member to aid in the positioning of the member.

Regarding claims 7 and 16, Globerman et al. disclose that the marker insert is secured to the marker housing by frictional engagement (Page 5, Lines 1-7).

Regarding claims 8 and 17, Globerman et al. disclose that the marker insert is secured in the marker housing by a protruding edge (Figure 9, Ref. Number 16).

Regarding claim 11, Globerman et al. disclose of a marker housing embodiment that is substantially elliptical (Figure 8, Ref. Number 14).

2. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over
Globerman et al. (WO 97/33534) in view of Boatman et al. (USPN 5,632,771)
and further in view of Imran (USPN 6,022,374).

Regarding claim 15, Globerman et al. disclose a stent with radiopaque marker inserts, however they lack the teaching of the diameter of the inserts. Imran teaches of a stent with radiopaque markers that include an insert and a projection with a diameter of 0.015 inches (Column 3, Lines 17-29) to fit within the eyelet. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of

Globerman et al. to have marker inserts with a diameter of 0.02 inches to frictionally engage the marker housing.

Response to Arguments

Claims 18-31 have been canceled.

Regarding Applicant's arguments to the anticipation of the claimed invention one Page 2, Paragraph 1 of Paper No. 8 filed 29 May 2003, the Examiner points out that the use of the transitional phrase "comprising" is open-ended and does not exclude additional features (see MPEP 2111.03).

Applicant's arguments, see Paper No. 8, filed 29 May 2003, with respect to the rejection(s) of claim(s) 1-14, 16-23 and 25-27 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Boatman et al. (USPN 5,632,771).

Applicant's arguments, see Paper No. 8, filed 29 May 2003, with respect to the rejection(s) of claim(s) 15 under 103(a) has been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Boatman et al. (USPN 5,632,771).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg
July 29, 2003


David H. Willse
Primary Examiner